

REMARKS

This invention provides for improved pasted pharmaceutical or veterinary formulations as well as methods of treating the various disease states associated with these formulations. This invention also provides for an improved method for manufacturing the paste formulations.

Pursuant to 37 CFR 1.136(a), Applicant petitions the Assistant Commissioner to extend the time period for Applicant to respond to the Requirement for an Election of Species by one (1) month, i.e., up to and including September 10, 2000. A check for \$ 110.00 is enclosed to cover the cost of this petition. It is believed that no further fee is required for the consideration of this Amendment. However, if a fee is due, the Assistant Commissioner is authorized to charge such fee, or credit any overpayment, to Deposit Account 50-0320.

This Amendment corrects an obvious typographical error made with respect to the dependency of claim 3.

In response to the Requirement for an Election of Species, Applicant elects COX-2 inhibitors as the therapeutic agent and oral administration as the dosage form. Claims 1, 4, 6, 7, 11, 12, 13, 22, 23, 24, 26, 27, 30, 31 and 44 read upon the elected formulation. Applicant traverses this requirement for an election of species if this means that the Examiner will not extend the search if the elected species are found allowable. It is requested that the Examiner indicate on the record how the requirement for an election of species: i.e., as a searching aid or as a restriction requirement.

Applicant respectfully traverses this Requirement if it is used by the Examiner as a restriction requirement. Applicant urges that the Restriction is improper as it does not establish

that searching all the species constitutes an undue burden to the Office and because it is contrary to public policy. Accordingly, modification or withdrawal of this Requirement is respectfully requested.

The MPEP lists two criteria for a proper Restriction Requirement. First, the invention must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner if restriction is not required. *Id.* The MPEP directs the examiner to search and examine an entire application "[i]f the search and examination of an entire application can be made without serious burden, ...even though it includes claims to distinct or independent inventions." *Id.*

The inventive compositions are directed to novel paste formulations comprising an effective amount of a therapeutic agent, fumed silica, a viscosity modifier, a carrier and, optionally, other formulation aids such as absorbents, colorants, stabilizers, surfactants or preservatives. The present invention also provides for an improved process to make the inventive paste products. The formulations of the present invention exhibit good chemical and physical stability over the shelf life and maintain the chemical integrity, texture, consistency and viscosity over a wide temperature range and may be used for a wide range of therapeutic agents. As the formulations all contain fumed silica, a viscosity modifier and a carrier, the searches for any of the formulations overlap. Since the searches overlap, Applicant urges that searching all the paste formulations, while distinct, would not constitute an undue burden to the Office.

Further, it is respectfully urged that restricting the claims in the manner suggested in the Requirement constitutes an undue burden to Applicant as well as the public. Hence, it is against public policy. If followed, the Requirement would require Applicant to file numerous patent applications, depending upon how the Examiner uses the election of species. The cost of

prosecuting and maintaining so many patents is unreasonable in view of the fact that Applicant cannot ascertain at this point how many inventions the Patent Office considers to be present in the present claims. Further, under GATT, the period of exclusivity for any patents which issue from the divisional application is greatly reduced. Similarly, the public is inconvenienced as they will not know whether or not Applicant will file divisional applications to the remaining subject matter. Accordingly, the public will not know if they can practice the remaining invention without infringing future patent applications.

Accordingly, in view of the foregoing, reconsideration and modification of this Restriction Requirement is requested and an early action on the merits is earnestly solicited.

Respectfully submitted,

FROMMER LAWRENCE & HAUG LLP
Attorneys for Applicants

By: 

Mark W. Russell
Reg. No. 37,514
(212) 588-0800

RECEIVED
SEP 21 2000
TC 3700 TOLLE ROOM